

AB-378U

10/698,097

REMARKS

This is a full and timely response to the final Official Action mailed November 30, 2005. Applicant hereby petitions for a two-month extension of time to respond and authorizes payment of the requisite fee below. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Request for Continued Examination:

Applicant hereby requests Continued Examination for this application and entry and consideration of this amendment consequent thereto.

Status of Claims:

Claims 1-23 are currently pending for further action.

Prior Art Issues--Anticipation:

The outstanding Office Action rejected claims 1-4, 7, 10-12, 14, 16, 17, 19 and 21-23 as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 6,066,163 to John ("John"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

In a neurostimulator implant system having multiple electrode contacts through which electrical stimuli are applied to tissue of a patient, and wherein an evoked compound action potential (ECAP) occurs in the tissue when an electrical stimulus of sufficient intensity has been applied to the tissue, and wherein the presence or absence of an ECAP in response to an applied stimulus serves as a useful objective indicator relative to the operation and functionality of the implant system, an improved method of eliciting an ECAP comprising the steps for:
generating electrical stimuli with selectable degrees of intensity;
delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, *the electrode contacts being arranged such that the electrical current*

AB-378U

10/698,097

output by the at least two electrode contacts combines to provokes a single ECAP in the tissue and, while delivering the electrical stimuli, gradually adjusting the intensity of the electrical stimuli and monitoring for the occurrence of said single ECAP with another separate electrode contact of the multiple electrode contacts;

noting the intensity of the applied electrical stimuli when the ECAP is first observed;

using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(emphasis added).

It should be noted that claim 1 recites at least two electrode contacts that are used together to output an electrical current that combines to produce a single occurrence of an evoked compound action potential (ECAP). In contrast, John, like the prior art cited previously, fails to teach or suggest the use of at least two electrode contacts used together to output an electrical current to produce an ECAP.

As stated in Applicant's specification, "[t]raditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact. There are cases where such application of a stimulus to a single electrode contact do[es] not evoke a suitable action potential." (Applicant's specification, paragraph 0003). In contrast, Applicant has discovered that by driving two or more electrodes, either simultaneously or in rapid succession, to output an electrical current, an ECAP can be more effectively and reliably evoked. According to Applicant's specification, "electrical stimuli are applied simultaneously (or sequentially at a rapid rate) on selected small groups of electrodes while monitoring the ECAP on a nearby electrode. The presence of an observable ECAP advantageously validates operation of the implant device at a time when the patient may be unconscious or otherwise unable to provide subjective feedback." (Applicant's specification, paragraph 0024).

AB-378U

10/698,097

In contrast, John teaches a direct brain stimulation system with electrodes dispersed over different portions of the brain. (See John, Fig. 1). John does not ever teach or suggest the claimed method in which at least two electrodes are used together to produce a single occurrence of an ECAP. The Office Action fails to cite any portion of John which provides such a teaching. Rather, it appears that the Office Action is attempting to read subject matter into the John reference that is not actually there.

Moreover, claim 1 also recites that the "at least two electrode contacts output an electrical current into the tissue, *while gradually adjusting the intensity* of the electrical stimuli and while monitoring for the occurrence of an ECAP with another separate electrode contact." John does not teach or suggest outputting an electrical current into tissue *while gradually adjusting the intensity* of the electrical stimuli and while also monitoring for the occurrence of an ECAP with another separate electrode contact. The Office Action fails to even address this subject matter of claim 1 and fails to indicate how or where such subject matter is taught by John.

Consequently, no *prima facie* case of unpatentability has been made. Specifically, John does not teach or suggest much of the subject matter of claim 1. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 1 and its dependent claims based on John should be reconsidered and withdrawn.

AB-378U

10/698,097

Similarly, independent claim 10 recites:

In a neurostimulator implant system having multiple spaced-apart electrode contacts and means for delivering electrical stimuli through selected ones of the multiple electrode contacts for the purpose of stimulating tissue of a patient, an improved neurostimulator implant system adapted to elicit an evoked compound action potential (ECAP) from the tissue of the patient when an electrical stimulus of sufficient intensity is applied to the tissue, comprising:

means for generating electrical stimuli with selectable degrees of intensity;

means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, while gradually adjusting the intensity of the electrical stimuli, *the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue;*

means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of said single ECAP, said separate electrode contact that is monitored being located near the at least two multiple electrode contacts to which the electrical stimuli is delivered;

means for noting the intensity of the applied electrical stimuli when the ECAP is first observed; and

means for using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(emphasis added).

As demonstrated above, John fails to teach or suggest the claimed “means for delivering the electrical stimuli to at least two of the multiple electrode contacts, *the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue.* (emphasis added). Additionally, John fails to teach or suggest “gradually adjusting the intensity of the electrical stimuli” in connection with “means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of an ECAP. For at least these reasons, the rejection of claim 10 and its dependent claims based on John should also be reconsidered and withdrawn.

AB-378U

10/698,097

Independent claim 16 recites:

A cochlear implant system comprising:
means for applying a stimulus pulse to at least two electrodes of multiple electrodes, either simultaneously or sequentially at a fast rate, said at least two electrodes outputting an electric current into patient tissue in order elicit an objectively-determinable response indicative of appropriate stimulation levels for the system, *the electrodes being arranged such that the electrical current output by the at least two electrodes combines to provokes a single objectively-determinable response;*
and

means for detecting said objectively-determinable response.
(emphasis added).

John fails to teach or suggest a "cochlear implant system." John does not even mention a cochlear implant system. For at least this reason, the rejection of claim 16 and its dependent claims based on John should be reconsidered and withdrawn.

Moreover, as demonstrated above, John fails to teach or suggest a system that comprises means for applying a stimulus pulse with at least two electrodes outputting an electric current that combines to provoke a single, objectively-determinable response indicative of appropriate stimulation levels for the system. For at least this reason, the rejection of claim 16 and its dependent claims based on John should be reconsidered and withdrawn.

Additionally, John does not teach or suggest a means used to determine "appropriate stimulation levels for the system." The final Office Action fails to address this subject matter of claim 16 or to indicate how or where such subject matter is taught by John. All that John says on this subject is that "the optimal level of stimulation is chosen by the patient by a criterion where the patient again attains comfort." (John, col. 2, lines 50-52). Thus, John also fails to teach or suggest the claimed means that "elicit an objectively-determinable response indicative of appropriate stimulation levels for the system."

AB-378U

10/698,097

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. Consequently, for at least these reasons, the rejection of claim 16 and its dependent claims based on John should also be reconsidered and withdrawn.

Independent claim 21 recites:

An implantable stimulator system for stimulating tissue, said stimulator system comprising:

a plurality of electrodes each of which is configured to selectively output an electrical current to the tissue, wherein the system is configured to output an electrical current with two or more of the plurality of electrodes, simultaneously or in rapid succession, *wherein the current output by the two or more electrodes acts together on the tissue so as to evoke a single neural response*;

an electrode for detecting the neural response caused by the electrical current output by the two or more electrodes;

wherein detection of said single neural response is used by said system along with parameters defining said electrical current that evoked said neural response to determine initial stimulation parameters for said implantable stimulator.

(emphasis added).

As demonstrated amply above, John fails to teach or suggest a system with a plurality of electrodes "configured to output an electrical current with two or more of the plurality of electrodes, simultaneously or in rapid succession, *wherein the current output by the two or more electrodes acts together on the tissue so as to evoke a single neural response*."

(emphasis added). John also fails to teach or suggest that "detection of said single neural response is used by said system along with parameters defining said electrical current that evoked said neural response to determine initial stimulation parameters for said implantable stimulator."

AB-378U

10/698,097

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. Consequently, for at least these reasons, the rejection of claim 21 and its dependent claims based on John should also be reconsidered and withdrawn.

Prior Art Issues—Obviousness:

Dependent claims 5, 6, 8, 9, 13, 15, 18 and 20 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of John and U.S. Patent No. 6,175,767 to Doyle. This rejection is respectfully traversed for at least the following reasons.

The final Office Action states that "John and Doyle both teach of multichannel implantable hearing devices, and thus teach of analogous arts." (Action of 11/30/05, p. 3). *This is clearly incorrect.*

As noted above, the teachings of John are related to direct brain stimulation "for the treatment of traumatic brain injury and the often resulting persistent vegetative state or 'coma' or the treatment of other brain dysfunctions such as movement disorders." (John, col. 1, lines 8-11). John does not even mention an implantable hearing device, contrary to the misplaced assertions of the Office Action. Doyle, in contrast, is actually in the field of implantable ear stimulators.

Consequently, one of skill in the art would not have had any motivation to combine the teachings of John and Doyle as suggested in the final Office Action. Rather, the final Office Action has failed to explain how or why one of skill in the art would have been

AB-378U

10/698,097

motivated to combine the teachings of Doyle's implantable hearing device with John's direct brain stimulator.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed Cir. 1992)." M.P.E.P. § 2143.01 (emphasis added). For at least this additional reason, the rejection of claims 5, 6, 8, 9, 13, 15, 18 and 20, based on the erroneous combination of John and Doyle, should be reconsidered and withdrawn.

Double Patenting;

Lastly, the recent Office Action provisionally rejected claims 1-20 based on the judicially-created doctrine of obviousness-type double patenting in view of claims 1-6 of co-pending Application No. 10/698,098. As this is merely a *provisional* rejection, Applicant is not required to take any action in response at the present time.

If co-pending Application No. 10/698,098 should be issued prior to the present application, Applicant will consider filing a terminal disclaimer to address the double patenting issue. However, Applicant takes no position at this time as to whether the claims of the present application and those of co-pending Application No. 10/698,098 might, at some future time, present an actual double patenting issue.

AB-378U

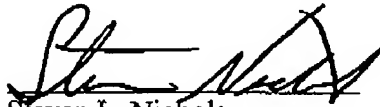
10/698,097

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: April 27, 2006


Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095

(801) 572-8066
(801) 572-7666 (fax)

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number ~~571-273-8300~~ on April 27, 2006. Number of Pages: 24


Rebecca R. Schow